

Notice of Allowability	Application No.	Applicant(s)	
	10/030,138	STOTT, KELVIN	
	Examiner	Art Unit	
	Samuel W. Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/22/05.
2. ☒ The allowed claim(s) is/are 1-26,41 and 45.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>11/23/05</u>. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
|---|--|

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DETAILED ACTION

This Office action is in response to the applicants' amendment filed 9/22/05, which amends claims 1-26, and cancels claims 27-40 and 42-44 has been entered. The following Office action is applied to the pending claims 1-26, 41 and 45.

EXAMINER'S AMENDMENT

An Examiner's Amendment to the record appears below. Should the change and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with John C. Holman on 11/23/2005. Applicants agree to the examiner proposed amendment to claims 1-26, 41 and 45 (see below).

Amendments to the claim:

The pending claims 1-26, 41 and 45 have been amended as follows. Please replace the previous claims with the claims shown below.

Claim 1 (*Amended*): Change "A chemical compound or composition comprising peptide, wherein" to "**A peptide comprising**"; and in claim item c), line 7, change "lie along either the first edge or the second edge" to "lie along the first edge **and** the second edge".

Claim 2 (*Amended*): Change "The chemical compound or composition" to "**The peptide**".

Claim 3 (*Amended*) Change "The chemical compound or composition" to "**The peptide**".

Claim 4 (*Amended*): Change "The chemical compound or composition" to "**The peptide**".

Claim 5 (*Amended*): Change "The chemical compound or composition" to "**The peptide**".

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Claim 6 (*Amended*): The ~~chemical compound or composition~~ peptide according to claim 1, wherein the side chain of each α -D-amino acid residue in the β -strand-forming[-] section allows or promotes the β -strand forming section to form a β -strand.

Claim 7 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 8 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 9 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 10 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 11 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 12 (*Amended*): The ~~chemical compound or composition~~ peptide according to claim 1, wherein the side chain of one or more α -D-amino acid residues in the p-strand-forming section contains a detectable group which allows the ~~compound or composition~~ peptide to be traced or detected.

Claim 13 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 14 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 15 (*Amended*): The ~~chemical compound or composition~~ peptide according to claim 1 wherein the target p-strand is formed by the Alzheimer's A β peptide, and the β -strand-forming section binds specifically as a β -strand to part or all of the KLVFFAE sequence of (SEQ ID NO: 5) within the target β -strand in the parallel orientation, thereby forming a parallel β -sheet complex wherein consecutive residues of the β -strand-forming section

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lie ~~diagonally~~ directly opposite consecutive residues of the ~~KLVFFAE sequence~~ SEQ ID NO:5 in the same order.

Claim 16 (*Amended*): The ~~chemical compound or composition~~ peptide according to claim 1 wherein the target β -strand is formed by the Alzheimer's A β peptide, and the β -strand-forming section binds specifically as a β -strand to part or all of the KLVFFAE sequence of (SEQ ID NO: 5) within the target β -strand in the antiparallel orientation, thereby forming an antiparallel β -sheet complex wherein consecutive residues of the β -strand-forming section lie ~~diagonally~~ directly opposite consecutive residues of the ~~KLVFFAE sequence~~ SEQ ID NO:5 in reverse order.

Claim 17 (*Amended*): Change "The chemical compound or composition" to "**The peptide**".

Claim 18 (*Amended*): Change "The chemical compound or composition" to "**The peptide**".

Claim 19 (*Amended*): Change "The chemical compound or composition" to "**The peptide**".

Claim 20 (*Amended*): Change "The chemical compound or composition" to "**The peptide**".

Claim 21 (*Amended*): The ~~chemical compound or composition~~ peptide according to claim 20, wherein the functional component is selected from the group consisting of:

- a component which strengthens the binding of the β -strand-forming section to the target β -strand;

- a component which enhances specificity of association of the β -strand-forming section with the target β -strand;

- a component which enables the β -strand-forming section to cross cell membranes, the blood-brain barrier and other biological barrier;

- a component which causes the ~~compound/composition~~ peptide to target specific organs, cells, or molecules;

- a component which allows the ~~compound/composition~~ peptide to be traced or detected;

- an atom or group that contains a radioactive or magnetically active nucleus;

- a fluorescent, coloured, or other spectroscopically detectable group;

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a group which contains an unpaired electron and thereby acts as a spin label;
a group which contains the 2, 2, 5, 5-tetramethyl-1-pyrrolidinyloxy (PROXYL) group or the 2, 2, 6, 6-tetramethyl-1-piperidinyloxy (TEMPO) group;
a solid matrix, resin, or support;
an enzyme, hormone, antibody, transcription factor, or other protein molecule;
a group that binds specifically to a particular protein; and
a cytotoxic molecule.

Claim 22 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 23 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 24 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 25 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 26 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 41 (*Amended*): A pharmaceutical ~~compound or composition~~ comprising the peptide according to claim 1.

Claim 45 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Amendments to the specification:

In abstract is amended as follows (in one paragraph and in a separate sheet):

Peptide is disclosed which comprises D-enantiomers of amino acids and is capable of interacting with other β -strand structure to form β -sheet, wherein said peptide is selectively N α -

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substituted in one edge (first) of the β -strand-forming section of said peptide while the other edge (second) in the opposite orientation to the first edge in view of peptide backbone plane remains $N\alpha$ -unsubstituted. Such the $N\alpha$ -substituted peptide is capable of preventing association of said peptide with other β -strand (target) but permits interaction of said peptide with target β -strand in separate peptide-containing molecules through the $N\alpha$ -unsubstituted edge. The peptide is useful for preventing β -strand association or aggregation.

Objection to the drawings:


The drawing filed 9/22/05 is objected to because (i) the SC (side chain) moieties presented in the "peptide ribbon plane" of said drawing is inappropriate in which α -carbons to which the SC moieties link appear to be missing; and (ii) explanation or legend of the drawing should not be presented in the drawing, e.g., "*SCs extend from either side of the peptide (or ribbon) plane- i.e., into/out of the paper*"; it should belongs to brief description of the drawing thereof. In addition, the drawing thereof does not contain a label indicating Figure number in accordance with Figures 1-7 filed 1/28/02.

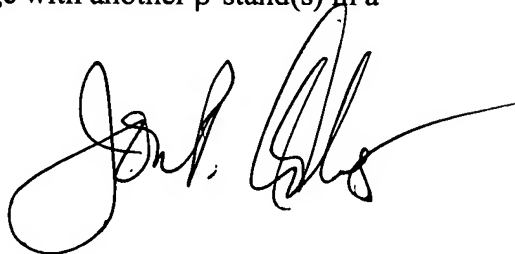
The drawings (Figures 6 and 7) filed 1/28/02 are object to because of the absence of Labeling indicating the figure number thereof.

The following is an Examiner's Statement of Reasons for Allowance:

The rejections under 35 USC 103 in the office action mailed 7/27/05 are withdrawn in light of that the applicants' amendment to claims obviates the rejections. The Prior art does not fairly teach or suggest, or provided motivation with regard to $N\alpha$ -substitution at one edge but $N\alpha$ -unsubstitution at opposite edge of a β -stand forming section of a D-amino acid containing peptide wherein the said edges are in accordance with the drawing filed 9/12/05. Such the formed $N\alpha$ -substituted peptide hinders the interaction of said edge with another β -stand(s) in a separate peptide-containing molecule.

Therefore, claims 1-26, 41 and 45 are allowed.


Samuel W. Liu, Ph.D.
Art Unit 1653, Examiner
November 28, 2005


JON WEBER
SUPERVISORY PATENT EXAMINER

Abstract

Peptide is disclosed which comprises D-enantiomers of amino acids and is capable of interacting with other β -strand structure to form β -sheet, wherein said peptide is selectively $N\alpha$ -substituted in one edge (first) of the β -strand-forming section of said peptide while the other edge (second) in the opposite orientation to the first edge in view of peptide backbone plane remains $N\alpha$ -unsubstituted. Such the $N\alpha$ -substituted peptide is capable of preventing association of said peptide with other β -strand (target) but permits interaction of said peptide with target β -strand in separate peptide-containing molecules through the $N\alpha$ -unsubstituted edge. The peptide is useful for preventing β -strand association or aggregation.